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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,101	06/27/2003	John S. Ng	PHA 4199.1	8072
321	7590	08/19/2004	EXAMINER	
SENNIGER POWERS LEAVITT AND ROEDEL ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			SOLOLA, TAOFIQ A	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,101

Applicant(s)

NG ET AL.

Examiner

Taofiq A. Solola

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 17-57 and 66-93 is/are pending in the application.
- 4a) Of the above claim(s) 17-57 and 66-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 87-93 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/27/03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1</u> . | 6) <input type="checkbox"/> Other: ____. |

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Claims 17-57, 66-93, are pending in this application.

Claims 1-16, 58-65, are canceled.

DETAILED ACTION

Election/Restriction

1. The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. For these reasons provided below, restriction to one of the following Groups is required under 35 U.S.C. 121, wherein an Group is a set of patentably distinct inventions of a broad statutory category (e.g. Compounds, Methods of Use, Methods of Making, etc.):

I. Claims 17-20, drawn to a process of making compound VII, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

II. Claims 21-22, 42-46, drawn to a process of making compound VIII, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

III. Claims 23-24, drawn to a process of making compound XXXI, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

IV. Claims 25-26, 36-37, drawn to a process of making compound XIV, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

V. Claims 27-28, drawn to a process of making compound XV, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

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VI. Claims 29-30, 35, drawn to process of making compounds XXXII and XXII, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

VII. Claims 31-32, drawn to a process of making compound XXI, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

VIII. Claims 33-34, drawn to a process of making compound XXII, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

IX. Claims 38-39, drawn to a process of making compound XXV, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

X. Claims 40-41, drawn to a process of making compound XXVI, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XI. Claims 47-48, drawn to a process of making compound 104, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XII. Claim 49, drawn to a process of making compound 102, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XIII. Claims 50-52, drawn to a process of making compounds 101 and XXXVI, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XIV. Claim 53, drawn to a process of making compound II, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XV. Claims 54-57, 66-86, drawn to a process of making compound I, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XVI. Claims 87-93, drawn to compound I, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300

(CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984),

Restriction of a Markush group is proper where the compounds within the group either (1)

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do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. 103.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventors must be amended in compliance with 37C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37CFR 1.17(i).

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can **set forth** a group of compounds, which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

Rationale Establishing Patentable Distinctiveness Within Each Group

Each Invention Set listed above is directed to or involves the use or making of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over either of the other inventions, i.e. they are patentable over each other. Chemical structures, which are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holdings of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137

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USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The above Groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

Inventions of Groups XVI and XV are related as product and process of making respectively. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process of Grob et al., US 4,559,332.

The inventions of groups I to XV are not related. The inventions are drawn to different processes of making different products. Each process has different starting material.

In addition, because of the plethora of classes and subclasses in each of the Groups, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Janet Hendrickson on 8/13/04 a provisional election was made with traverse to prosecute the invention of group XVI, claims 87-93. Therefore, claims 17-57, 66-86, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory of Rejoinder

The following is a recitation of M.P.E.P. §821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

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The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 87-93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are product-by-process claims and are independent claims but fail to recite the representatives of -A-A-, -B-B-, and R1 to R9. Instead, the claims refer to the definitions in claims 66-86. Therefore, claims 87-93 are indefinite.

Claim 93 is drawn to a compound made according to the process of claim 87. However, 87 is not a process claim, it is a compound claim. Therefore, claim 93 is indefinite.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 87-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grob et al., US 4,559,332.

Applicant claims compounds of formula I made by different processes of claims 66-86 (Product-by-process). The formula has several substituents listed in claim 66 most of which are the same as in the compounds of Grob et al..

Determination of the scope and content of the prior art (MPEP §2141.01)

Grob et al., teach compounds of formula I, and several species of the compound. See the abstract, columns 1-3 and the claims. All the substituents of formula I are claimed by applicant.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Grob et al., is that the instant compounds are isomeric with the compounds of Grob et al. Also, applicant is claiming the compounds as product-by-process.

Finding of prima facie obviousness---rational and motivation (MPEP §2142.2413)

First, patentability in a product-by-process claim is determined by the product. Even if applicant's process of making the compounds is new and novel, the compounds are unpatentable if they are the same or obvious from a prior art. *In re Thorpe et al.*, 227 USPQ 964 (CAFC 1985).

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Second, a novel and useful compound, which is an isomer of a compound of prior art, is prima facie obvious where the new compound is not shown to possess novel and unexpected utilities. *In re Norris*, 84 USPQ 458 (1950). Therefore, the instant invention is prima facie obvious from the teaching of Grob et al. Having known the compounds of Grob et al., one of ordinary skill in the art would have known to claim the isomers at the time the invention was made.

The motivation is from well-established principle of structure-activity relationship. That is, compounds having similar structures are expected to have similar biological and chemical activities. Also, it is well known in the art that isomers often have the same activity but in degrees.

Drawing

Figures 4-5 are objected to. The labels on the figures are hand written. They should be in print.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1626

August 17, 2004